## REMARKS

Claims 39, 40, 42, 45, 47, 49-70, and 72-83 and 85 are currently pending in the application.

Claims 39, 45, 47, 50, 55, 59, 66, and 72 have been amended to clarify the subject matter presented therein. Specifically, claim 39 has been amended to read, "An anhydrous composition formulated for topical delivery consisting of: (a) an anhydrous vehicle consisting of about 1 to about 50 percent by weight of ethanol, (b) a penetration enhancer consisting of about 1 to about 50 percent by weight of propylene glycol, (c) a humectant consisting of polyethylene glycol and glycerin, in a combined amount of about 10 to about 80 percent by weight, (d) ketoconazole in an amount of about 0.5 to about 3 percent by weight, and (e) optionally one or more component selected from the group consisting of an emollient, a chelating agent, a pH adjuster, an antioxidant a viscosifier, a fragrance, a UV stabilizer, and a sunscreen, wherein the composition contains a gelling agent and is formulated as an anhydrous gel." Claims 45, 47 and 49 have been amended to reflect changes in dependency. Claims 50, 55, 59 and 66 have been amended to reflect proper antecedent bases for the elements recited therein. Claim 72 has been amended to read "consisting of" hereby making recitation of the phrase "...does not contain a retinoid or steroid..." redundant, and on these grounds the latter has been struck from the claims.

New claim 85 is presented and is directed to "An anhydrous composition formulated for topical delivery consisting essentially of: (a) an anhydrous vehicle consisting of about 1 to about 50 percent by weight of ethanol, (b) a penetration enhancer consisting of about 10 to about 50 percent by weight of propylene glycol, (c) a humectant consisting of polyethylene glycol and glycerin, in a combined amount of about 10 to about 80 percent by weight, (d) ketoconazole in an amount of about 0.5 to about 3 percent by weight, (e) a gelling agent, and optionally one or more components selected from the group consisting of emollients, chelating agents, pH adjusters, antioxidants, viscosifiers, colorants, fragrances, UV stabilizers, and sunscreens, wherein the composition is formulated as an anhydrous gel and does not contain a retinoid or a steroid."

Claims 1-38, 43 and 73 were previously cancelled, and claims 46, 48, 71 and 84 are presently cancelled without prejudice or disclaimer to the subject matter recited therein.

Amendment to or cancellation of any claim in this application is done solely for the purposes of advancing prosecution and in no way constitutes an admission of the validity of any objection or rejection made against any of the instant claims.

Support for the amendments and new claim may be found through out the application and claims as originally filed. No new matter has been added within the meaning of 35 USC §132. Therefore, entry of the amendments and new claim is respectfully requested.

In the Decision, grounds of rejection I-IV and X-XII were maintained, while the grounds for rejection V-IX were vacated. Specifically, the vacated grounds of rejections were:

V. Rejection of claims 39-42, 44-51, 55-61, 63, 65-71, and 84 under 35 U.S.C. §103(a) as being rendered obvious by the combination of Cauwenbergh and Wang.;

VI. Rejection of claims 62 and 64 under 35 U.S.C. §103(a) as being rendered obvious by the combination of Cauwenbergh and Wang, as further combined with Papa;

VII. Rejection of claims 52-54 under 35 U.S.C. §103(a) as being rendered obvious by the combination of Cauwenbergh and Wang, as further combined with McCrea;

VIII. Rejection of claim 72 under 35 U.S.C. §103(a) as being rendered obvious by the combination of Cauwenbergh and Wang, as further combined with Papa and McCrea; and

IX. Rejection of claims 74-83 under 35 U.S.C. §103(a) as being rendered obvious by the combination of Cauwenbergh and Wang, as further combined with Thornfeldt.

The rejections maintained are:

I. Rejection of claim 84 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description rejection;

II. Rejection of claims 39-42, 44-62, 64, 66-71, 74, 75, 77-80, and 83 under 35 U.S.C. §103(a) as being rendered obvious by Sun;

III. Rejection of claims 63, 65, and 72 under 35 U.S.C. §103(a) as being rendered obvious by the combination of Sun and Kabara;

IV. Rejection of claims 76, 81, and 82 under 35 U.S.C. §103(a) as being rendered obvious by the combination of Sun and Thornfeldt;

X. Rejection of claims 39-42, 44-72, and 84 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8-16, 22, 25, and 26 of U.S. Patent No. 6,238,683;

XI. Rejection of claims 74-83 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8-16, 22, 24-26 of U.S. Patent No. 6,238,683 as combined with Thornfeldt; and

XII. Provisional rejection of claims 39-42, 44-72, and 74-84 under the judicially created obviousness-type double patenting as being unpatentable over claims 48-53, 56-62, and 86-118 of copending Application No. 09/562,376.

Applicants acknowledge that grounds I, X, XI and XII were not addressed in the appeal, and therefore those rejections were maintained on their original merits by the Board. The remaining grounds for rejections, i.e. II, III and IV, were addressed on appeal and will be addressed herein accordingly.

## A. Rejection of Claim 84 under 35 USC §112, first paragraph, written description

The rejection of claim 84 under 35 USC §112, first paragraph, as failing to comply with the written description requirement was not argued on appeal and, as such, was maintained by the Board. Specifically, this rejection of claim 84 was described in the Official Action dated February 1, 2007, as follows:

> ...the specification does not provide support for the recitation that the composition does not contain propylene carbonate, as recited in the claim....the specification is silent as to the use or non-use of ...propylene carbonate...

Applicants respectfully traverse this rejection. Applicants believe the instant specification does support the claim element in question to the degree that one of skill in the art would recognize it as part of the instantly claimed subject matter thereby fulfilling the written description requirement. However, solely in the interest of advancing prosecution, claim 84 has been cancelled. As such, the basis for this rejection has been removed and withdrawal of the rejection of claim 84 under 35 USC §112, first paragraph is respectfully requested.

### B. Rejection of claims 39-42, 44-62, 64, 66-71, 74, 75, 77-80, and 83 under 35 U.S.C. §103(a) as being rendered obvious by Sun

The Board, beginning on page 4 of the Decision, maintains the rejection of claims 39-42, 44-62, 64, 66-71, 74, 75, 77-80, and 83 under 35 U.S.C. §103(a) as being unpatentable over Sun, stating:

> Sun describes anhydrous compositions that encompass the claimed composition, and specifically lists all of the components of claim 39...the disclosure of Sun renders the composition of 39 obvious...Appellants assert further that they have shown unexpected results...[and] that Sun teaches away from compositions that do not include a steroidal agent...Appellants' showing of unexpected results, when weighed with the evidence as a whole, is not sufficient to demonstrate the non-obviousness of the claimed composition...the purported unexpected results are not commensurate in scope with the composition of claim 39, as Appellants have only compared a single formulation of the claimed composition, and have not demonstrated by evidence or argument to why the ordinary artisan would find the results to be representative of the full scope of the composition of claim 39. As to Appellants' argument that Sun teaches away from compositions that do not contain a steroid or retinoid...Sun specifically exemplifies compositions that do not contain a steroid or retinoid. Thus, Sun renders obvious compositions that both contain and do not contain a steroid or retinoid...

Applicants respectfully traverse this rejection. Applicants respectfully submit that the rejection of the identified claims as being obvious over Sun should be withdrawn on the grounds that Sun requires the presence of propylene carbonate as the primary solvent. In contract, propylene carbonate does not fall within the scope of the instant claims.

Specifically, Applicants respectfully submit that Sun teaches the essential and required use and presence of propylene carbonate as the primary solvent in the disclosed compositions. See, col. 3, lines 43-44 and 51-52; col. 5, lines 25-26 and 33-35; and the Examples. While Applicants strenuously disagree with the Board and the Examiner with respect to the alleged obviousness of the instant claims in view of Sun, Applicants, solely for the sake of advancing prosecution, have amended claim 39 to recite the transitional phrase "consisting of". Thus, Applicants submit that propylene carbonate, a required element of Sun, is clearly not included within the scope of the instantly rejected claims.

As such, one of skill in the art would have no motivation to modify the teachings of Sun to remove the required solvent to arrive at the instantly claimed anhydrous compositions. Accordingly, the grounds for the rejection of claims 39-42, 44-62, 64, 66-71, 74, 75, 77-80, and 83 under 35 U.S.C. §103(a) as being unpatentable over Sun have been obviated, and Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

### C. Rejection of claims 63, 65 and 72 under 35 U.S.C. §103(a) as being rendered obvious by the combination of Sun and Kabara

The Board, on page 10 of the Decision, maintains the rejection of claims 63, 65 and 72 under 35 U.S.C. §103(a) as being unpatentable over the combination of Sun and Kabara based on the general reasoning given in support of the obviousness rejection based on Sun alone, which was discussed above.

Applicants respectfully traverse this rejection. Applicants respectfully submit that the rejection of the identified claims as being obvious over the combination of Sun and Kabara should be withdrawn on the grounds that Sun requires an element not

present in the instant claims. As stated above, Sun requires the presence of propylene carbonate as the primary solvent. In contrast, propylene carbonate does not fall within the scope of the instantly claimed subject matter.

Again, Sun requires the essential use and presence of propylene carbonate as the primary solvent. See, col. 3, lines 43-44 and 51-52; col. 5, lines 25-26 and 33-35; and the Examples. Applicants do not agree with the opinion of the Board or the Examiner regarding the alleged obviousness of the instant claims in view of the combination of Sun and Kabara. However, in order to advance prosecution Applicants have amended claim 72 to recite the transitional phrase "consisting of". Likewise, claims 63 and 65 depend indirectly from claim 39, which has been similarly amended. Thus, Applicants submit that propylene carbonate, a required element of Sun, is clearly not included within the scope of the instantly rejected claims.

As such, one of skill in the art would have no motivation to modify the teachings of Sun to remove the required solvent in combination with the teachings of Kabara to arrive at the instantly claimed anhydrous compositions. Accordingly, the grounds for the rejection of claims 63, 65 and 72 under 35 U.S.C. §103(a) as being unpatentable over the combination of Sun and Kabara have been obviated. Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

### D. Rejection of claims 76, 81 and 82 under 35 U.S.C. §103(a) as being rendered obvious by the combination of Sun and Thornfeldt

The Board, on page 10 of the Decision, maintains the rejection of claims 76, 81 and 82 under 35 U.S.C. §103(a) as being unpatentable over the combination of Sun and Thornfeldt based on the general reasoning given in support of the obviousness rejection based on Sun alone, which was discussed above.

Applicants respectfully traverse this rejection. Applicants respectfully submit that the rejection of the identified claims as being obvious over the combination of Sun and Thornfeldt should be withdrawn on the grounds that Sun requires the presence of propylene carbonate as the primary solvent of the disclosed compositions. As detailed above, propylene carbonate does not fall within the scope of the instant claims.

The primary solvent required by Sun is propylene carbonate, which is a required and essential element of the compositions of this reference. See, col. 3, lines 43-44 and 51-52; col. 5, lines 25-26 and 33-35; and the Examples. Applicants strenuously disagree with the Board and the Examiner regarding the alleged obviousness of the instant claims in view of the combination of Sun and Thornfeldt. However, in order to advance prosecution Applicants have amended the independent claims 39 and 72 from which claims 76, 81 and 81 indirectly depend to recite the transitional phrase "consisting of". Thus, Applicants submit that propylene carbonate, a required element of Sun, is clearly not included within the scope of the instantly rejected claims.

As such, one of skill in the art would have no motivation to modify the teachings of Sun to remove the required solvent in combination with the teachings of Thornfeldt to arrive at the instantly claimed anhydrous compositions. Accordingly, the grounds for the rejection of claims 76, 81 and 82 under 35 U.S.C. §103(a) as being unpatentable over the combination of Sun and Thornfeldt have been obviated. Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

**E. Nonstatutory obviousness-type double patenting rejection of claims 39-42, 44-72, and 84 as being unpatentable over claims 1-3, 8-16, 22, 25, and 26 of U.S. Patent No. 6,238,683**

Claims 39-42, 44-72 and 84 stand rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8-16, 22, 25 and 26 of U.S. Patent No. 6,238,683. Applicants note that claim 84 has been cancelled and is no longer a subject of this rejection.

The instant application and U.S. Patent 6,238,683 are commonly owned. Therefore, a terminal disclaimer pursuant to 37 C.F.R. §1.321(c) is submitted herewith. Submission of this terminal disclaimer is made solely for the purposes of advancing prosecution and does not constitute an admission of the obviousness of any of the claims of the instant application over cited U.S. Patent No. 6,238,683.

Accordingly, the rejection of claims 1-3, 8-16, 22, 25 and 26 on the grounds of nonstatutory obviousness-type double patenting has been overcome. Withdrawal of the rejection is respectfully requested.

**F. Nonstatutory obviousness-type double patenting rejection of claims 74-83 stand rejected on the ground of as being unpatentable over claims 1-3, 8-16, 22, 24-26 of U.S. Patent No. 6,238,683 as combined with Thornfeldt**

Claims 74-83 stand rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8-16, 22 and 24-26 of U.S. Patent No. 6,238,683 as combined with Thornfeldt.

The instant application and U.S. Patent 6,238,683 are commonly owned. Therefore, a terminal disclaimer pursuant to 37 C.F.R. §1.321(c) is submitted herewith. Submission of this terminal disclaimer is made solely for the purposes of advancing prosecution and does not constitute an admission of the obviousness of any of the claims of the instant application over cited U.S. Patent No. 6,238,683 as combined with Thornfeldt.

Accordingly, the provisional rejection of claims 74-83 on the grounds of nonstatutory obviousness-type double patenting has been overcome. Withdrawal of the rejection is respectfully requested.

**G. Provisional rejection of claims 39-42, 44-72, and 74-84 under the judicially created obviousness-type double patenting as being unpatentable over claims 48-53, 56-62, and 86-118 of copending Application No. 09/562,376.**

Claims 39-42, 44-72, and 74-84 stand provisionally rejected under the judicially created obviousness-type double patenting as being unpatentable over claims 48-53, 56-62, and 86-118 of copending Application No. 09/562,376.

Applicants respectfully request that the Examiner hold this rejection in abeyance until such time as the Examiner indicates there is successful resolution of the claim rejections noted above. Applicants, at that time, will either address the rejection or file a terminal disclaimer over copending U.S. Patent Application No. 09/562,376.

## CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of all rejections outstanding in this application. If there are any other fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 14-0112.

The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

Respectfully submitted,

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